

# **Apparatus for Determining the Amount of Milk Breast-Fed To a Baby by Convective Heat Transfer**

## **BACKGROUND OF THE INVENTION**

### Field Of The Invention

This invention relates to baby care products and methods and more particularly to an apparatus to determine and monitor the volume of human milk breast fed by a nursing mother to a baby.

### Description of the Related Art

Breast feeding is known as the best method of feeding a child in its first year of life. The benefits of breastfeeding can be both physical and psychological for both the mother and the child. Nutrients and antibodies are passed to the baby while hormones are released into the mother's system during breast feeding. Breast milk, when fed directly from the breast, provides immediately available nutrients with no wait and is at body temperature. Breast fed babies have a decreased risk for several infant conditions including Sudden Infant Death Syndrome (SIDS). The sucking technique required of the infant encourages the proper development of both the teeth and other speech organs. The many health benefits of breastfeeding have been well documented. Extensive research, especially in recent years, documents diverse and compelling advantages to infants, mothers, families, and society from breastfeeding and the use of human milk for infant feeding. These include health, nutritional, immunologic, developmental, psychological, social, economic, and environmental benefits.

It is not uncommon for a mother and child to have difficulties breastfeeding in the beginning, but most of these problems resolve in the early weeks.

A small percentage (between 2 & 3%) of women are unable to provide a full day's calories. Even among this small group, it is feasible to continue breastfeeding while supplementing with donated breast milk or artificial baby milk. Many of these mothers breastfeed exclusively by using thin tubing taped to the breast to deliver the supplementary food. This is called a supplementary nursing system, or SNS.

Since the nutritional requirements of the baby must be satisfied solely by the breast milk in breastfeeding, it is important for the mother to maintain a sufficient supply for the infants needs and supplement when necessary to promote proper growth and development of the infant. To determine the volume of milk consumed by a baby during breast-feeding sessions, it is known to weigh the baby before the session as well as during and immediately after the session. This is a cumbersome process and the scales required are rather sensitive and thus expensive.

### OBJECT OF THE INVENTION

An object of the present invention is therefore to solve the above discussed problems and to create an inexpensive device and method of measuring the quantity of milk breast fed to an infant without the use of scales.

### SUMMARY OF THE INVENTION

According to the invention there is provided an apparatus for determining the amount of human milk supplied to a feeding baby during a breast-feeding session. This apparatus includes a nipple shield adapted to be mounted on the nipple region of a breast of a mother; a tube or tubes defining an outlet through which milk passes to the feeding baby; and a thermal dilution gauge to measure the amount of milk passing through the outlet. The nipple shield may be nipple-shaped and may be made of silicon rubber or any other suitable material. Preferably, the tube may be made of stainless steel, rigid plastic, or any other suitable material for the transmission of a liquid.

The thermal dilution gauge may comprise a heater and two resistive temperature detectors (RTD), or only two RTD, which can be mounted outside or inside the tube(s), as separate components or as one chip. Electronic circuitry, a data communication cable, or electromagnetic transmitter, connecting the thermal dilution gauge to the CPU and/or display unit, may be mounted and/or integrated on the nipple shield.

The display means may comprise a liquid crystal or similar display, and/or may be adapted to print a graphical representation of the data received from the thermal dilution gauge.

The display means may comprise a number of switches for entering data (e. g. the age of the baby, etc.) or for selectively display of the amount of milk per session, the accumulating amount of milk in several sessions, and previously consumed milk (memory switch).

### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a diagrammatic illustration of the apparatus according to the invention connected to the breast of a breast-feeding mother;

Figure 2 is a diagrammatic cross section of the nipple shield, illustrating the construction of the apparatus.

Figure 3 is a view of the tube, partially cross-sectioned, mounted with a micro-machined thermal dilution gauge, according to the invention;

Figure 4 is an isometric view of one of the suggested micro-machined thermal dilution gauges, according to the invention.

Figure 5 is a diagram of two possible arrangements of the thermal dilution gauge, and its control circle.

Figure 6 is a perspective view of the printed circuit board and connector which interface with the digital display unit.

Figure 7 is a front view of the digital display device with attached connector.

### DETAILED DESCRIPTION OF THE INVENTION

The invention will now further be described, by way of example only, with reference to the accompanying diagrams. The apparatus, in Figure 1, for measuring the volume of human milk breast-fed to a baby comprises a nipple shield **2**, a data communications cable **3** and a CPU and/or display unit **4**. In use, the nipple shield **2** is mounted on the breast **1** of a mother. The feeding baby (not shown) is allowed to feed through the nipple shield **2**.

The nipple shield **2** is made of three separate layers of silicon rubber **5**, **6** and **8**. Layer **8**, as shown in Figure 2, is a thickened part of layer **5** and they are both manufactured as one part during the molding process. Layer **8**, which is thicker than the rest of the nipple shield, provides a cover for the tube **9**. Layer **6** has holes **7** in it and is preferably attached to layer **5** by using medical-grade silicon rubber glue, in a way that forms a space (cavity) between layers **6** and **8**.

The milk is allowed to flow through holes **7** in the inner layer **6** of the shield from several conduits in the mother's nipple. The milk is temporarily accumulated in the space between layers **6** and **8**. There is only one tube **9** in the apparatus, through which the milk is delivered to the baby. The purpose of the cavity between layers **6** and **8** is to gather milk, running from several conduits in the mother's nipple, through the holes **7** and allow it to flow through the single tube **9**. The driving force for the milk flow is the suction power of the baby. The volume of milk taken in by the baby is measured by the thermal dilution gauge **11**.

As shown in Figure 5 there are two basic structures for the thermal dilution gauge **11**, one with a heater **14** and two sensors **13**, **15**, and the second with only two sensors **13**, **15**. The sensors may be thermopiles or resistance temperature detectors (RTDs). The thermal dilution gauge **11** as shown on Figure 4 may be a micro-machined chip, with the thermopiles or RTDs **13**, **15** forming a part of it. Optionally, a heater **14** may be incorporated between the thermopiles or RTDs **13**, **15**. The thermal dilution gauge **11**, as a micro-machined chip, has several soldering pads to which wires **20** in a data communications cable **3** are soldered.

Figure 3 shows the tube **9** with mounted thermal dilution gauge **11**. All of the milk flow **12** passes through the precision manufactured tube **9** during nursing. The thermal dilution gauge **11** of Figure 4 may be a micro-machined chip. The thermopiles or sensors **13**, **15** form a part of thermal dilution gauge **11**, and have several soldering pads to which wires **20** in a data communications cable **3** are soldered. Optionally, a heater **14** may be incorporated between the sensors **13**, **15**. The sensors **13**, **15** with the soldered wires are assembled into the thermal dilution gauge **11**, which is attached to the tube **9**, in a special niche in the wall of the tube **9**.

The tube **9** with thermal dilution gauge **11** is put inside a nipple shield mold, where the silicon rubber forming the nipple shield **2** is injected. The tube **9** is substantially perpendicular to the surface of the nipple shield **2**.

A small flexible PCB (printed circuit board) **26**, as in Figure 6, with an EPROM **24** and a connector **28** on it, are then soldered to the opposing end of the wires **20** in the communication cable **3**. This flexible PCB **26** is then covered in a small flexible plastic housing. The housing **30** has an opening for the connector **28**, to allow the user to connect the nipple shield **2** to the processing and display unit **4**. The EPROM **24** (memory device) contains the specific calibration data of a particular tube/thermal dilution gauge of a particular nipple shield.

This EPROM **24** is used to store calibration data as each tube/thermal dilution gauge is different and must be individually calibrated. Using a calibration process, a table or an equation is generated which represents the specific signal that corresponds to the specific flow rate. This table is memorized in the EPROM **24**. These calibrations take into account minor variations in the size of the tube **9** and the distance apart of the sensors **13**, **15**, as well as the optional heater **14**.

Figure 7 shows the display **40** as a part of the processing CPU and display unit **4** which is separately connectable by connector **28** to any individual nipple shield **2**. The processing and display unit **4** includes another PCB with electronic components, a microprocessor and an LCD as the display **40**, all contained within a plastic housing. Additionally, there are a series of selectable buttons **42** for control and selection on the display unit **4**.

The microprocessor in the processing unit **4** samples the signal from the measuring unit many times per second. The microprocessor uses these samples and the calibration data in the EPROM **24** to convert the signal to flow data. The flow data is then integrated over time to give the accumulating amount of milk. This amount is then shown on the LCD display **40**.

As shown in Figure 5 there are two basic structures for the thermal dilution gauge **11**, one with a heater **14** and two sensors **13**, **15**, and the second with only two sensors **13**, **15**. In these two arrangements, the breast milk **12** flows in the tube **9** and over the surface of the thermal dilution gauge **11**. The flow of the breast milk **12** is such that it would first pass over the upstream thermopile or sensor **13** then over the heater **14**, if it exists, and then over the downstream thermopile or sensor **15**. The measuring principle for each structure is now described.

In a device with a heater plus two thermopiles, the heater **14** is heated to ~2-3 degrees Celsius, above the expected temperature of the liquid (~36 degrees C). When there is no flow, the two sensors **13, 15**, sitting at the same distance from each side of the heater **14**, will register the same temperature. When there is a flow **12**, the temperature registered by the upstream thermopile **13** will be lower than the temperature registered by the downstream sensor **15**. The two sensors **13, 15** are connected through an electronic bridge **16**. The different temperatures registered by the sensors **13, 15** will make the bridge **16** generate an analog signal. This analog signal represents the voltage difference between the two sensors. The signal increases as the flow **12** increases. The signal is amplified using an amplifier **17** for reading by the display unit **4**.

In a device with only two thermopiles and no separate heater, the two thermopiles **13, 15** also serve as heaters and are constantly heated to ~2-3 degrees C, above the expected temperature of the liquid (~36 degrees C). When there is no flow **12**, there is no temperature difference between the two thermopiles **13, 15**. When there is a flow **12**, the temperature of the downstream thermopile **15** will be higher than the temperature of the upstream **13** thermopile. This is due to the fluid being heated slightly by the upstream thermopile **13** before reaching the downstream thermopile **15**. The two thermopiles are connected through an electronic bridge **16**. The different temperatures registered will make the bridge **16** generate an analog signal, which represents the voltage difference between the two sensors. This analog signal will increase as the flow **12** increases. This signal is amplified using an amplifier **17** for reading by the display unit **4**.

In both arrangements, since the temperature difference between the two detectors is directly proportional to the mass flow of the milk, a highly accurate and repeatable flow measurement is obtained.

Thus, the apparatus according to the invention provides the nursing mother in real time with an indication of the volume of milk taken in by a feeding baby. It would accordingly no longer be necessary to follow the cumbersome weighing process hereinbefore described.

The invention is described in detail with reference to a particular embodiment, but it should be understood that various other modifications can be effected and still be within the spirit and scope of the invention.